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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
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GREENBERG TRAURIG LLP (LA)				EXAMINER	
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SANTA MONICA, CA 90404				PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/053,387	DING ET AL.
Examiner	Art Unit	
Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 November 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,3,5-8,10,13,16,18-32 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-8,10,13,16 and 18-31 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 32 and 35-39 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date, _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for reconsideration filed 11/14/2008.

Claims 1, 4, 9, 11, 12, 14, 15, 17, 33 and 34 have been canceled.

Claims 2, 3, 5-8, 10, 13, 16, 18-32, 35-39 are pending.

1. This application contains claims 2, 3, 5-8, 10, 13, 18-31 drawn to an invention nonelected with traverse in the reply filed on 03/12/2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Claim 16 has been withdrawn as directed to nonelected invention without traverse during telephone conversation with Mr. Wall on 09/12/2007.

Claims 32, 35-39 are included in the prosecution.

The following rejection has been discussed in the previous office action, and is maintained for reasons of record:

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 32, 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of 4,738,257 ('257) and US 4,335,026 ('026).

US '257 teaches wound dressing comprises wound contact layer comprising elastomeric continuous phase with particulate water-absorbing hydrocolloid phase dispersed therein (abstract; col.5, lines 9-13). The wound dressing increases fluid absorption without including dislodgment and leakage and facilitates one piece removal with minimal wound irritation (col.2, 42-48; col.3, lines 27-30). The hydrocolloid

particulate is selected from CMC, pectin, and karaya gum, and forms 40-60% of wound contacting layer (col.5, lines 40-55; col.6, lines 25-30). The elastomeric phase comprises 20-35% polyisobutylene (PIB), 5-25% cross-linker such as styrene-olefin-styrene that reads on styrenic block copolymer claimed by claim 37, 1-7% oils that read on plasticizer claimed by claim 32, and further comprises superabsorbent and/or fumed silica that read on additives claimed by claim 38 (col.5, lines 65-68; col.6, lines 1-12, 25-30, 38-47, 59-68; col.10, 44). The oils, superabsorbent, and petrolatum disclosed by the reference all read on therapeutic agents claimed by claim 35. The reference further teaches material to improve the dry tack of the composition comprising polymer of dicyclopentadiene (col.6, lines 53-57).

Although US '257 suggests polymers of dicyclopentadiene wherein dicyclopentadiene reads on diene part of the polymer, and although the reference teaches elastomeric polymer forming the continuous phase, however, the reference does not explicitly teach EPDM as polymer containing diene as required by claim 32.

US '026 teaches an adhesive composition for application to the skin as an adhesive bandage and tape suitable for covering wound and having decreased resistance to peel removal while maintaining high shear resistance in air and in water (abstract; col.1, lines 7-17; col.3, lines 50-55). The preferred adhesive composition comprises ethylene-propylene-diene monomer terpolymer wherein the ratio of ethylene to propylene is 3:1, i.e. 75% ethylene and 25% propylene (col.2, lines 57-61). The composition further comprises, styrene block copolymer in an amount of 25-42%,

elastomer stabilizer, plasticizer, and anti-oxidants, which read on the active agent (col.2, lines 20-33, 42-44; col.3, lines 30-33; col.5, lines 27-29; col.5, examples I-III).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprises wound contact layer comprising elastomeric phase with particulate water-absorbing hydrocolloid phase dispersed therein wherein the elastomeric phase comprises PIB and polymer of dicyclopentadiene as disclosed by US '257, and replace the polymer of dicyclopentadiene with EPDM polymer having 75% ethylene and 25% propylene disclosed by US '026 because US '026 teaches that adhesive comprising EPDM polymer having this ratio of ethylene and propylene is preferred and suitable for wound dressing, and provides decreased resistance to peel removal while maintaining high shear resistance in air and in water, with reasonable expectation of having hydrocolloid adhesive composition comprising EPDM polymer having ratio of ethylene to propylene of 3:1, polyisobutylene, and hydrophilic particles wherein the hydrocolloid adhesive composition is non-irritating to the skin and has decreased resistance to peel removal while maintaining high shear resistance in air and in water.

Response to Arguments

6. Applicant's arguments filed 11/14/2008 have been fully considered but they are not persuasive.

Applicants argue that the Examiner provides improper reasoning by stating that though Meyer does not explicitly teach EPDM, it would have been obvious to take the

elastomeric phase comprising PIB and dicyclopentadiene (DCPD) as disclosed by Meyer, and replace the DCPD with the EPDM as disclosed by Balinth. This is because the only place in Meyer that discusses DCPD is column 6, lines 53-58, and was described as "a tackifier resin for improving dry tack for the barrier layer and because Balinth teaches a composition consisting of an olefin terpolymer (EPDM), a solid tackifier, and some other components (i.e. natural rubber, liquid plasticizer, reinforcing filler, and stabilizer). The fact that Balinth teaches a solid tackifier in addition to EPDM indicates that EPDM is not the solid tackifier. Nowhere in Balinth does it mention DCPD.

In response to this argument, it is argued that the present claims are directed to composition, and all the elements of the composition are disclosed by combination of the references. Meyer teaches diene compound, irrespective of its intended use or function. Meyer used the diene compound in wound dressing. Balinth reference desired to include diene compounds in its composition for treating wounds and preferred EPDM having 75% ethylene and 25% propylene because it provides wound dressing having the advantage of decreased resistance to peel removal while maintaining high shear resistance in air and in water. One having ordinary skill in the art would have been replaced one diene compound by another or further add EPDM to the composition already comprising DCPD as permitted by the claims' language. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In considering the disclosure of the reference, it is proper to take into

account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). The invention as a whole is taught by the combination of Meyer and Balinth.

Applicants argue that the conclusion that combining Meyer and Balinth yields a composition comprising EPDM and PIB is not valid, as such is achieved only by improper hindsight reasoning with Applicant's teachings.

In response to this argument, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. *KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL.* (2007).

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicants argue that the present specification discloses that combining PIB with tackifiers is commonly found in the art. However, claim 32 directed to composition comprising EPDM and PIB, but does not require tackifiers.

In response to this argument, it is argued that the expression "comprising" of the claims' language does not exclude the presence of other ingredients, active or inactive such as tackifiers, even in major amounts.

Applicants argue that the combination of EPDM and PIB yields a compound that possesses unexpected properties and is therefore not taught or suggested by Meyer or Balinth. Applicant describes in paragraph [0009] and [0010] of the specification that the disadvantage of a hydrocolloid composition comprising only PIB was that it had low integrity when it absorbed a great amount of fluid, US 3,339,465. US 4,166,051 describes a PIB composition having butyl rubber added as an integrity enhancer. However, the total absorbency of the composition compared to only PIB was reduced. The expected property of a composition comprising PIB and another hydrophobic polymer, EPDM, would also be a reduced total absorbency. However, as evidenced in TABLE 2 of Applicant's specification, the EPDM based hydrocolloid compositions as taught by Applicant (examples 8-11) maintained high absorption while obtaining

enhanced integrity. None of the cited references explicitly suggest or teach the combination of EPDM and PIB because the advantage of a maintained high absorption was not to be expected.

In response to this argument, it is noted that tables 1-3 of the present specification, that compare the properties of the present compositions with the prior art compositions regarding integrity of the composition and absorbency do not show unexpected results. The tables showed that the prior art US 4,551,490 provides integrity of 9 and absorption up to 245, while the present compositions provides similar, less or equivalent integrity and absorbency. For example, examples 2 and 11 showed integrity of 9 that is the same as US '4,551,490. Examples 1, 8, 10, and 11 showed integrity of 8 that is less than US 4,551,490 and example 12 showed more reduced integrity of 6. Therefore, no unexpected results were presented regarding integrity due to combination of PIB and EPDM. The saline absorbency of the present examples showed low absorbency that are lower than the prior art, example 16 showed 71, and the prior art showed higher absorbency.

The unexpected results presented in the specification do not commensurate is scope with the present claims. Tables 1-3 showed many variation in the amount of the ingredients of each composition, and also showed variation in the ingredients of the compositions. No single composition showed unexpected integrity and absorbency that is distinguished over the prior art, and no showing of which ingredient provides such improvement over the prior art. Examples 8-11 showed high absorbency, however, this

property is a result of the presence of the hydrophilic particles, and not due to the combination of PIB and EPDM.

In addition, regarding the arguments of unexpected superior results in the instant specification, it is the examiner's position that the data in the specification regarding low integrity and high fluid absorbency are not unexpected results and therefore can not rebut *prima facie* obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of the claims at issue." *In re Corkhill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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